REQUEST FOR INFORMATION/SOURCES SOUGHT NOTICE - CRANBERRY PRODUCT RESOURCE/SERVICE CENTER:

This Request For Information (RFI) /Sources Sought Notice (SS) is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Center for Complementary and Alternative Medicine (NCCAM). The purpose of this RFI/SS is to identify potential sources that are interested in and capable of performing the work described herein. NCCAM welcomes comments from all individuals and concerns. The NCCAM does not intend to award a contract on the basis of responses nor otherwise pay for the preparation of any information submitted or NCCAM's use of such information. Acknowledgement of receipt of responses will not be made, nor will respondents be notified of NCCAM's evaluation of the information received. As a result of this RFI/SS, the NCCAM may issue a Request for Proposal (RFP). However, should such a requirement materialize, no basis for claims against the NCCAM shall arise as a result of a response to this RFI/SS or the NCCAM's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

Request for Information:

The NCCAM seeks input and comment on its plan to develop a future solicitation for a RESOURCE/SERVICE CENTER (hereinafter referred to as Center). At some undetermined future date, the NCCAM intends to award a single contract for a Center, able to:

1. Support the preparation, characterization, standardization, and maintenance of a supply of cranberry products and matching placebos with concomitant quality control and quality assurance. These products will be used in NIH-supported research, specifically (but not exclusively) for basic and clinical research on the role of cranberry (*Vaccinium macrocarpon*) in the prevention and treatment of urinary tract infections (UTI). Products of primary interest are cranberry juice cocktail, concentrate, and encapsulated powders. It is important that the cranberry products for NIH-supported research be of a high quality. The Center shall provide adequate information about the source, collection, storage, processing, extraction and purification process, formulation, bioavailability, stability, and safety of the product(s) in order to meet Food and Drug Administration (FDA) requirements for the filing of Investigational New Drug (IND) Application(s). Grantees in response to a companion initiative for basic and clinical research on the role of cranberry in the prevention and treatment of UTI (see concept at http://nccam.nih.gov/fi/concepts/aug2001/cranberry.html) will be required to use the cranberry products provided by the Center. After award of these grants and the Center contract, the Center and the research grantees will determine type of products, quantity, and dose needed for the variety of research projects. The Center will be responsible for developing, packaging, storing, inventorying and distributing the products based on grantee needs.

2. Provide services to individuals or organizations seeking natural product analyses of

products used in NIH-supported research on a fee for service basis. These analyses may be for the purposes of identifying source material; determining contaminants; identifying chemical profiles; or assessing stability. Developing analytic methodologies may be a pre-requisite to conducting some analyses.

The NCCAM seeks to determine the pool of potentially interested and qualified applicant organizations to aid in the design of a possible future solicitation for a Center that can:

- Accurately identify *Vaccinium macrocarpon* and other plant species, and their macro- and microscopic physical characteristics (e.g., DNA fingerprinting);

- Provide a standard, high-quality source of the raw material (*V. macrocarpon* only);

- Develop and document substantiated, qualitative and quantitative analytic methods for the analysis of crude materials (*V. macrocarpon* and other plant and animal species);

- Identify the chemical profile for active constituents and inactive marker compounds (*V. macrocarpon* and other plant and animal species);

- Identify and describe the species and plant parts from which the standardized product is derived, how it is derived (or extracted), the form in which it is provided (*V. macrocarpon* only);

- Conduct stability testing (*V. macrocarpon* and other plant and animal species);

- Establish protocols for production, under Good Manufacturing Practices of the standardized dosage forms (*V. macrocarpon* only);

- Develop and maintain a Drug Master File at the Food and Drug Administration, and file an application(s) for an Investigational New Drug (*V. macrocarpon* only).

- Provide (e.g., package, store, inventory, and distribute) the standardized product to the NIH-sponsored grantees (*V. macrocarpon* only);

Additionally please comment on your organization's ability to:

- Develop and supply, in a timely manner, the three cranberry products (e.g., juice, concentrate, encapsulated powder) simultaneously.

- Work and contract with suppliers, when it is necessary to obtain the raw source material or any product thereof (*V. macrocarpon*) from a supplier other than itself.

- Provide fee-for-service tasks as related in paragraph 2 above.

Sources Sought:

Interested organizations should submit a capability statement of approximately 10 pages that details the ability to perform the aspects of the effort described above. All proprietary information should be marked as such. Responses will be reviewed only by NIH personnel and will be held in a confidential manner.

All respondents are asked to indicate the type and size of your business organization, e.g., large business, small business, small disadvantaged business, women-owned business, 8(a), hubzone, historically black college or minority institution, educational institution, profit/non-profit hospital, or other non-profit organization in your response. In the event an RFP is issued, North American Industry Classification System (NAICS) code 541710 with a size standard of 500 employees is being considered.

Responses are due no later than 3:00 pm Eastern Prevailing Time on October 13, 2001. Please submit three (3) copies of your response to the attention of: Robert D. Barnie, Contracting Officer, Epidemiology and Support Section, Research Contracts Branch, OM, National Cancer Institute, and if using regular U.S. mail - Executive Plaza South, Suite 620, MSC 7224, Bethesda, MD 20892-7224.; or if hand delivered or using a courier service – 6120 Executive Boulevard, Rockville, MD 20852. Facsimile responses may be submitted by FAX to 301-480-0241 or email responses may be sent to rb355w@nih.gov.

Telephone inquiries should be addressed to Robert Barnie at 301-435-3779.